

Introduced by Senator Price

February 8, 2010

An act to add Section 1643.3 to, and to repeal and add Section 1639.01 of, the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL'S DIGEST

SB 975, as introduced, Price. Tissue bank licensing.

Existing law requires the State Department of Public Health to establish regulations, as specified, governing the operation and maintenance of tissue banks licensed in California. Existing law allows for the revocation or suspension of a tissue bank's license for specified reasons. Violation of these provisions is a misdemeanor.

This bill would require the collection, processing, storage, or distribution of human tissue for use in California to comply with the 12th edition of Standards for Tissue Banking as published by the American Association of Tissue Banks, and would require future amendments of these standards to be adopted as regulations, if approved by the department. This bill would also allow the department to impose on licensed tissue banks, as an alternative to suspension or revocation of a tissue bank's license, a civil administrative penalty of \$100 per day of noncompliance per violation not to exceed an aggregate of \$3,000 per day.

Because the bill would make changes to the definition of a crime, it constitutes a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1639.01 of the Health and Safety Code
2 is repealed.

3 ~~1639.01. (a) Notwithstanding Section 1639, the state~~
4 ~~department shall adopt, on or before July 1, 2004, rules and~~
5 ~~regulations governing licensed tissue banks engaged in the~~
6 ~~collection of human musculoskeletal tissue, skin, and veins for~~
7 ~~transplantation in humans. The regulations shall be substantially~~
8 ~~based upon the criteria used by tissue bank trade associations in~~
9 ~~their respective accreditation processes including, but not limited~~
10 ~~to, those of the Eye Bank Association of America and the American~~
11 ~~Association of Tissue Banks, and the scientific and technical data~~
12 ~~submitted by individual tissue banks.~~

13 ~~(b) Regulations adopted by the state department, pursuant to~~
14 ~~subdivision (a), shall include minimum standards for all of the~~
15 ~~following:~~

16 ~~(1) Safe preservation, transportation, storage, and handling of~~
17 ~~tissue acquired or used for transplantation.~~

18 ~~(2) Testing of donors to determine compatibility when~~
19 ~~appropriate.~~

20 ~~(3) Testing or assessment of donors to prevent the spread of~~
21 ~~disease through transplantation.~~

22 ~~(4) Equipment.~~

23 ~~(5) Methods.~~

24 ~~(6) Personnel qualifications.~~

25 ~~(7) Any other area concerning the operation or maintenance of~~
26 ~~a tissue bank, not inconsistent with this chapter, as may be~~
27 ~~necessary to carry out this chapter.~~

28 ~~(c) On or before July 1, 2003, the department shall report to~~
29 ~~the appropriate policy and fiscal committees of the Legislature~~
30 ~~regarding the status of the proposed regulations.~~

31 SEC. 2. Section 1639.01 is added to the Health and Safety
32 Code, to read:

33 1639.01. (a) Notwithstanding Section 1639, no person shall
34 engage in the collection, processing, storage, or distribution of
35 human tissue unless the tissue is collected, prepared, labeled,

1 stored, and distributed in accordance with the standards set forth
2 in the 12th edition of Standards for Tissue Banking as published
3 by the American Association of Tissue Banks and in effect on May
4 1, 2008.

5 (b) Amendments to, or later editions of, the Standards for Tissue
6 Banking shall be adopted as regulations, upon approval of the
7 department, not later than 90 days after publication. This section
8 shall not be subject to the rulemaking requirements of Chapter 3.5
9 (commencing with Section 11340) of Part 1 of Division 3 of Title
10 2 of the Government Code.

11 SEC. 3. Section 1643.3 is added to the Health and Safety Code,
12 to read:

13 1643.3. As an alternative to revocation or suspension of a
14 license issued under this chapter, the department may impose an
15 alternative civil administrative penalty of one hundred dollars
16 (\$100) per day of noncompliance per violation, including an
17 immediate jeopardy violation, except that the aggregate penalty
18 per day shall not exceed three thousand dollars (\$3,000). This
19 penalty may be imposed only after notice and an opportunity to
20 respond in accordance with Section 100171.

21 SEC. 4. No reimbursement is required by this act pursuant to
22 Section 6 of Article XIII B of the California Constitution because
23 the only costs that may be incurred by a local agency or school
24 district will be incurred because this act creates a new crime or
25 infraction, eliminates a crime or infraction, or changes the penalty
26 for a crime or infraction, within the meaning of Section 17556 of
27 the Government Code, or changes the definition of a crime within
28 the meaning of Section 6 of Article XIII B of the California
29 Constitution.